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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,117

10/13/2005

Francois-Xavier Berthet

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06/06/2008

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B482

FIVE MOORE DR., PO BOX 13398

RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

06/06/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/523,117	<b>Applicant(s)</b> BERTHET ET AL.	
	<b>Examiner</b> Mark Navarro	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-22, 25-65, 69-80 and 82-115 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 17, 20, 22, 45, 50-52, 54-61, 82, 83, 85-88, 90, 93, 95, 96, 98, 103, 114 and 115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>multiple</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12,16,19,21,25-44,46-49,53,62-65,69-80,84,89,91,92,94,97,99-102 and 104-113.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-61, and 82-91 in the reply filed on February 18, 2008 is acknowledged.

Additionally, Applicants have replied to the species requirement with the following selections: the Neisserial adhesion as NspA, the autotransporter as Hsf, the toxin as FrpA/C, the iron acquisition species as TbpA high, the membrane associated species as OMP85, the down regulated gene as lgtB, the species as *N. meningitidis*, and the bacterial capsular species as *N. meningitidis*.

Accordingly, claims 1-17, 19-22, 25-65, 69-80, 82-115 are pending in the instant application. Claims 12, 16, 19, 21, 25-44, 46-49, 53, 62-65, 69-80, 84, 89, 91-92, 94, 97, 99-102, 104-113 are withdrawn from further consideration as being drawn to a non-elected invention or a non-elected species.

### ***Claim Rejections - 35 USC § 112***

1. Regarding claim 2, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1645

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5, 7-15, 17, 20, 22, 50-52, 54-61, 82, 85, 87, 90, 93, 95, 96, 98, 103, and 114-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Peak et al.

The claims are drawn to an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial adhesion associated protein.

Peak et al (WO 2001/055182) disclose of immunogenic compositions comprising Neisserial NhhA. (See claims). Note NhhA = Hsf as set forth on page 12 of Applicants specification). Peak et al further disclose of overexpressing the NhhA protein in a Neisserial meningitidis strain. (See Example 2).

Given that the immunogenic composition disclosed by Peak et al comprised an overexpression of NhhA/Hsf, and that it was inherently in the presence of other Neisserial adhesion proteins or toxins or Fe acquisition proteins or membrane associated proteins, the disclosure of Peak et al is deemed to anticipate the instantly filed claims.

3. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by US Publication 2005/232936.

The claim is drawn to an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial adhesion associated protein.

US Publication 2005/232936 disclose of an immunogenic composition comprising an outer membrane vesicle and an autotransporter antigen, NadA. (See claim 32).

4. Claims 1-15, 17, 20, 22, 50-52, 54-61, 82-83, 85-87, 90, 93, 95, 96, 98, 103, and 114-115 rejected under 35 U.S.C. 102(e) as being anticipated by US Publication 2003/0215469.

The claim is drawn to an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial adhesion associated protein.

US Publication 2003/0215469 discloses of an immunogenic composition comprising an outer membrane vesicle and an autotransporter antigen, Hsf. (See claim 8).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-15, 17, 20, 22, 45, 50-52, 54-61, 82, 83, 85-88, 90, 93, 95, 96, 98, 103, and 114-115 rejected under 35 U.S.C. 103(a) as being unpatentable over US Publication 2003/0215469 or Peak et al in view of US Publication 2007/087018.

The claim is drawn to an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial adhesion associated protein, wherein OMP 85 is upregulated.

The teachings of US Publication 2003/0215469 and Peak et al are set forth above.

Neither US Publication 2003/0215469 nor Peak et al teach of upregulating OMP 85.

US Publication 2007/087018 teach of immunogenic compositions for eliciting protective immune responses which comprise *Neisseria gonorrhoeae* and *N. meningitidis* OMP 85. (See abstract).

Given that 1) US Publication 2003/0215469 and Peak et al have taught of immunogenic compositions comprising both an autotransporter (Hsf) and various other *Neisseria* antigens, and that 2) US Publication 2007/087018 has taught of the desire for including OMP 85 in *Neisseria* immunogenic compositions for eliciting an immunogenic response, it would have been prima facie obvious to one of ordinary skill in the art to combine the OMP 85 as taught by '018 with the composition taught by '469 or Peak et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shannon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/  
Primary Examiner, Art Unit 1645  
May 26, 2008